

The listing of claims presented below replaces all prior versions and listings of claims in the application.

Listing of Claims

1. (Currently amended) A once-a-day controlled release pharmaceutical tablet composition for peroral administration consisting of a single unit fast release layer and a single unit extended release layer, which comprises 200mg micronized nimesulide having average particle size below 5 microns as an active drug ~~upto 99%~~ from 20% to 70% w/w of the tablet composition, one or more release controlling materials in an ~~effective~~ amount from 8% to 20% w/w to control the release of said micronized nimesulide from said composition and pharmaceutical excipients from ~~0% to 90% w/w~~ 30% to 60% w/w of the tablet composition, wherein said micronized nimesulide being present in the fast release layer and in the extended release layer and wherein said release controlling materials present in said extended release layer are biodegradable and are selected from the group consisting of methyl cellulose, ethyl cellulose, hydroxypropylmethyl cellulose, hydroxypropyl cellulose, cellulose acetate phthalate, cellulose acetate, cellulose acetate butyrate, cellulose acetate propionate, cellulose acetate trimellitate, ~~cellulose carboxymethyl ethers and their salts~~, hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate, carbomers, polyalkylene polyols, polycarbophils, gelatins, and gums ~~polyethylene oxides~~.
2. (Cancelled)
3. (Cancelled)
4. (Cancelled)
5. (Previously Presented) The composition as claimed in claim 1, further comprising release modifiers selected from the group consisting of wetting agents, solubilizers, surfactants, plasticizers, pore formers, pH modifiers and tonicity adjusting agents.
6. (Cancelled)
7. (Cancelled)

8. (Previously Presented) The tablet composition as claimed in claim 1, wherein the extended release layer further comprises polymers, selected from the group consisting of polycarbophils, carbomers, alginates, cellulose and cellulose derivatives, chitosan gums and lecithins.
9. (Previously Presented) The tablet composition as claimed in claim 5, wherein the release modifier is a pH modifier and is selected from the group consisting of sodium bicarbonate, hydrochloric acid, citric acid, malic acid, and tartaric acid.
10. (Previously Presented) The tablet composition as claimed in claim 5, wherein the release modifier is selected from the group consisting of fats, fatty acids and transesterification products of fats and fatty acids with polyols.
11. (Currently amended) A process for the manufacture of a once-a-day controlled release tablet composition for peroral administration consisting of a single unit fast release layer and a single unit extended release layer, which comprises mixing together micronized nimesulide having average particle size below 5 microns as an active drug up to 99% from 20% to 70% w/w of the tablet composition, one or more release controlling materials in an effective amount from 8% to 20% w/w to control the release of said micronized nimesulide from said composition and pharmaceutical excipients from 0% to 90% w/w 30% to 60% w/w of the tablet composition, wherein said micronized nimesulide being present in the fast release layer and in the extended release layer and wherein said release controlling materials present in said extended release layer are biodegradable and are selected from the group consisting of methyl cellulose, ethyl cellulose, hydroxypropylmethyl cellulose, hydroxypropyl cellulose, cellulose acetate phthalate, cellulose acetate, cellulose acetate butyrate, cellulose acetate propionate, cellulose acetate trimellitate, ~~cellulose carboxymethyl ethers and their salts,~~ hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate, carbomers, polyalkylene polyols, polycarbophils, gelatins, and gums ~~polyethylene oxides.~~

Claims 12-18 (cancelled)

19. (Currently amended) The composition according to claim 1 wherein the single unit fast release layer comprises micronized nimesulide having average particle size below 5 microns and one or more pharmaceutical excipients selected from diluents, binders, wetting agents, disintegrants and lubricants; and the single unit extended release layer comprises micronized nimesulide having average particle size below 5 microns and biodegradable release controlling material selected from the group consisting of methyl cellulose, ethyl cellulose, hydroxypropylmethyl cellulose, hydroxypropyl cellulose, cellulose acetate phthalate, cellulose acetate, cellulose acetate butyrate, cellulose acetate propionate, cellulose acetate trimellitate, ~~cellulose carboxymethyl ethers and their salts~~, hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate, carbomers, polyalkylene polyols, polycarbophils, gelatins, and gums ~~polyethylene oxides~~.

Claims 20-24 (cancelled)

25. (Currently amended) A once-a-day controlled release pharmaceutical tablet composition for peroral administration consisting of a coating, a single unit fast release layer and single unit extended release layer, which comprises 200 mg micronized nimesulide having average particle size below 5 microns as an active drug ~~upto 99% from 20% to 70% w/w~~ of the tablet composition, one or more release controlling materials in an ~~effective~~ amount from 8% to 20% w/w to control the release of said micronized nimesulide from said composition and pharmaceutical excipients ~~from 0% to 90% w/w~~ 30% to 60% w/w of the tablet composition, wherein said micronized nimesulide being present in the fast release layer and in the extended release layer and wherein said release controlling materials present in said extended release layer are biodegradable and are selected from the group consisting of methyl cellulose, ethyl cellulose, hydroxypropylmethyl cellulose, hydroxypropyl cellulose, cellulose acetate phthalate, cellulose acetate, cellulose acetate butyrate, cellulose acetate propionate, cellulose acetate trimellitate, ~~cellulose carboxymethyl ethers and their salts~~, hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate, carbomers, polyalkylene polyols, polycarbophils, gelatins, and gums ~~polyethylene oxides~~.

26. (Currently amended) A once-a-day controlled release pharmaceutical tablet composition for peroral administration consisting of a single unit fast release layer and a single unit extended release layer which comprises 200 mg micronized nimesulide having average particle size below 5 microns as an active drug ~~upto 99% from 20% to 70% w/w~~ of

the tablet composition, one or more biodegradable release controlling materials from in an ~~effective~~ amount from 8% to 20% to control the release of said micronized nimesulide from said composition and pharmaceutical excipients from ~~0% to 90% w/w~~ 30% to 60% w/w of the tablet composition, wherein the fast release layer comprises micronized nimesulide having average particle size below 5 microns, lactose, starch, colloidal silicon dioxide, polyvinylpyrrolidone, polyoxyethylene sorbitan monostearate, docusate sodium, magnesium stearate and croscarmellose sodium; and the extended release layer comprises micronized nimesulide having average particle size below 5 microns, lactose, polyvinylpyrrolidone, magnesium stearate, docusate sodium, hydroxypropyl methylcellulose, colloidal silicon dioxide and sodium lauryl sulphate wherein the hydroxypropyl methylcellulose present in said extended release layer is a biodegradable release controlling material.

Claims 27-31 (Cancelled)